Trans rectus sheath preperitoneal mesh repair (TREPP) versus transinguinal preperitoneal procedure (TIPP) for inguinal hernia repair: a multi-center randomized controlled trial.

Published: 24-07-2012
Last updated: 26-04-2024

Reduce postoperative chronic pain after open inguinal hernia repair.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40117

Source
ToetsingOnline

Brief title
The ENTREPPMENT trial: TREPP vs TIPP

Condition

- Other condition
- Connective tissue disorders (excl congenital)
- Soft tissue therapeutic procedures

Synonym
groin hernia, inguinal hernia

Health condition

liesbreuk herstel

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: eigen financiele middelen van de deelnemende centra

Intervention

Keyword: groin hernia, inguinal hernia, trans rectus sheath preperitoneal mesh repair (TREPP), transinguinal preperitoneal procedure (TIPP)

Outcome measures

Primary outcome

Postoperative chronic pain

Secondary outcome

Health status; recurrence; cost analysis; serious adverse events

Study description

Background summary

Optimal open preperitoneal inguinal hernia repair.

The current main problem after Lichtenstein (gold standard) is postoperative chronic pain.
TIPP has proven (in the TULIP trial) to reduce postoperative chronic pain compared to Lichtenstein, therefore we use TIPP as control itnervention in this trial.

A new technique has been developed: transrectus sheath preperitoneal mesh repair (TREPP), in which via open approach a polysoft mesh is positioned in the preperitoneal space. Results of the first 1000 patients show a low recurrence rate, comparable to Lichtenstein; and few patients with postoperative chronic pain.

This trial will compare TREPP with TIPP, in a randomized trial.

Study objective

Reduce postoperative chronic pain after open inguinal hernia repair.

Study design

RCT, multi center.
Randomisation: TREPP of TIPP.
Questionnaires with every follow up at outpatient department.

Intervention

TREPP or TIPP; both open preperitoneal mesh repair for inguinal hernia.

TIPP: via inguinal canal mesh positioning in the preperitoneal space
TREPP: via anterior rectus sheath mesh positioning in the preperitoneal space.

Study burden and risks

No other risk than normal operation risk.
Burden consists of 2 extra outpatient clinic visits.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6525GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

*primary, groin hernia, unilateral
*age >18 years and < 80 years
*ASA classification 1-3
*signed informed consent

Exclusion criteria

*recurrences
*scrotal hernia
*femoral hernia
*bilateral hernia
*ASA >3
*incarcerated hernia
*psychiatric disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2014
Enrollment:	800
Type:	Actual

Ethics review

Approved WMO Date:	24-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ISRTCN18591339
CCMO	NL38842.091.12